



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: October 6, 2016

Subject: Efficacy Review for Saginaw
EPA Reg. No. 67619-29 (DP Barcode: 434613, E-sub #12425)

From: Alison Clune
Product Science Branch
Antimicrobials Division (7510P)

Thru: Mark Perry, Team Leader
Product Science Branch
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To: Jacqueline Hardy, PM 34 / Thomas Luminello
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Clorox Professional Products Company
c/o PS&RC
P.O. Box 493
Pleasanton, CA 94566-0803

Formulation from the Label:

<u>Active Ingredient</u>	<u>% by wt.</u>
Ethanol	66.34%
Dipropylene glycol	5.31%
<u>Other Ingredients</u>	28.35%
Total	100.00%

I BACKGROUND

The product, Saginaw (EPA Reg. No. 67619-29), is an EPA-registered hospital disinfectant (bactericidal, virucidal, fungicidal), non-food contact hard and soft surface sanitizer, and fabric mildewstat for use in health care, institutional, commercial, and residential environments. The registrant is requesting to add emerging pathogens claims to the product label.

This data package contained a letter from the registrant to EPA (dated June 24, 2016), updated

terms of registration for the product (dated June 24, 2016), and the proposed label (dated 6/24/16). No studies were associated with this submission.

II LABEL

Note to PM: The following comments are based on clean label R0942111, dated 6/24/16.

1. The proposed label claims that the product, Saginaw, qualifies for emerging pathogens claims against enveloped, large non-enveloped, and small non-enveloped viruses when used according to the directions for use against the viruses listed on page 1 of the letter “Re: Update to terms of Registration for Saginaw, EPA Reg. No. 67619-29”, dated June 24, 2016.

These claims are acceptable, however the Terms of Registration should be revised to reflect the language in Attachment 1 of the Emerging Viral Pathogen Guidance document (https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf). In particular:

- The effective date of the guidance in both the master label and the updated Terms of Registration should be changed to August 19, 2016.
 - Statement 1 should specify that technical literature is that “distributed exclusively to health care facilities, physicians, nurses, and public health officials”, and “production should be changed to “product.”
 - Statement 3 must include the 24-month time limit for non-label communications related to an emerging pathogen as described in the guidance.
 - Statement 4 must specify that statements 1-3 “shall become immediately void and ineffective if registration for use against the supporting viruses in the above table is suspended or cancelled such that the product no longer qualifies for the emerging pathogens claim, or no longer meets the criteria for a disinfectant claim...”, as described in the guidance.
2. On page 7 of the proposed label, the directions for use to disinfect internal surfaces of toilet and urinal bowls by emptying the toilet bowl are not acceptable. However, if the use is limited to dry/vacuum flush/waterless toilets and urinals, directions for disinfection will be acceptable.
 3. On pages 7-8 of the proposed label, the optional fourth 9 in each claim may not be added, unless the claim refers only to a virus or group of viruses, excluding HIV-1. The cited data supporting bactericidal disinfection claims do not support a 4-log (99.99%) reduction in the numbers of these organisms. The studies were semi-quantitative studies that do not provide an exact quantitative measure of organism reduction. The cited data supporting virucidal disinfection claims support a 4-log (99.99%) reduction in infective virus, except Human Immunodeficiency Virus Type 1 (HIV-1).
 4. On pages 7 and 8 of the proposed label, the claims “Pseudomonacidal” and “Staphylocidal” should be qualified with the names of the organisms to which they refer.